

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|-------------------------------|---|----------------------------|
| BAUSCH & LOMB INCORPORATED & |) | |
| PF CONSUMER HEALTHCARE 1 LLC, |) | |
| |) | |
| Plaintiffs, |) | |
| |) | C.A. No. _____ |
| v. |) | |
| |) | JURY TRIAL DEMANDED |
| SBH HOLDINGS LLC, |) | |
| |) | |
| Defendant. |) | |

COMPLAINT

Plaintiffs Bausch & Lomb Incorporated (“Bausch & Lomb”) and PF Consumer Healthcare 1 LLC (“PF Consumer Healthcare 1”) (collectively, “Plaintiffs”), by their attorneys, hereby allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, including 35 U.S.C. § 271.

THE PARTIES

2. Plaintiff Bausch & Lomb is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman Street, Rochester, NY 14609, within this district.

3. Plaintiff PF Consumer Healthcare 1 is a limited liability company organized and existing under the laws of Delaware and having a place of business at 1209 Orange Street, Corporation Trust Center, Wilmington, DE, 19801.

4. Defendant SBH Holdings LLC (“SBH”) is a limited liability company organized and existing under the laws of Delaware with a principal place of business at 5047 FM

2920 Road, Spring, TX 77388. On information and belief, SBH does business as “ScienceBased Health.” On information and belief, SBH is doing business within this district.

NEW YORK LAWSUIT

5. On June 30, 2020, Plaintiffs filed suit against SBH for infringement of U.S. Patent Nos. 6,660,297 (“the ’297 Patent”) and 8,603,522 (“the ’522 Patent”) (collectively, “Patents-in-Suit”) in the United States District Court for the Western District of New York. *See Bausch & Lomb Inc. et al. v. SBH Holdings LLC*, C.A. No. 6-20-cv-06451 (W.D.N.Y) (“New York Lawsuit”).

6. On October 1, 2020, SBH moved to dismiss the New York Lawsuit for improper venue under Fed. R. Civ. P. 12(b)(3).

JURISDICTION AND VENUE

7. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and (b).

8. This Court has personal jurisdiction over SBH. SBH is a Delaware company. On information and belief, SBH, directly or through its alter ego, affiliates, or agents, develops, formulates, manufactures, markets, and sells vitamin products throughout the United States, including in Delaware. On information and belief, SBH regularly conducts and solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from services or things used or consumed in the State of Delaware. On information and belief, SBH transacts business within the State of Delaware related to Bausch & Lomb’s claims, and has engaged in systematic, pervasive, and continuous business contacts within the State of Delaware.

9. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

CLAIMS FOR RELIEF

COUNT 1: PATENT INFRINGEMENT OF U.S. PATENT NO. 6,660,297

10. Bausch & Lomb is a joint owner and licensee of all rights in the field of ophthalmology, including the right to enforce, of the '297 Patent which was duly and lawfully granted on December 9, 2003 to Stephen P. Bartels, Cara L. Baustian, George E. Bunce, Leon Ellenbogen, Frederick L. Ferris III, Jin Kinoshita, James C. Smith and David A. Souerwine for an invention in "Nutritional Supplement to Treat Macular Degeneration." PF Consumer Healthcare 1 is a joint owner of the '297 Patent. Pursuant to 35 U.S.C. § 207(a) and the exclusive license received from the U.S. government joint owner, including the right to enforce the '297 Patent, Bausch & Lomb can maintain this action without the U.S. government as a party. A true copy of the '297 Patent is attached as Exhibit A.

11. The '297 Patent describes and claims, among other things, methods and compositions useful as nutritional supplements for prevention, stabilization and/or treatment of visual acuity loss by reducing the risk of age-related macular degeneration and cataracts and for maintaining and preserving eye health and vision. The invention of the '297 Patent provides, *inter alia*, a formulation dosage of vitamin A in the form of beta-carotene (substituted or supplemented with lutein, zeaxanthine or a combination thereof), vitamin C, and vitamin E, as well as zinc and copper.

12. On or about September 10, 2007, a request for an *inter partes* reexamination of the '297 Patent was filed in the United States Patent and Trademark Office ("PTO"). On or about April 30, 2013, the PTO issued an *Inter Partes* Reexamination Certificate wherein the PTO determined: (1) claims 1-4, 10, 18 and 19 of the '297 Patent were patentable as amended; (2) claims 5, 6, 8, 9, 11, 12 and 14-17 of the '297 Patent were patentable and (3) new claims 22 through

32 were patentable. A true copy of the *Inter Partes* Reexamination Certificate for the '297 Patent is attached as Exhibit B.

13. Bausch & Lomb markets and sells products covered by the '297 Patent within this district and elsewhere in the United States, including but not limited to its PreserVision® AREDS and AREDS 2 Formula products, with notice to the public that such products are patented by affixing to the package of those products a label identifying the '297 Patent.

14. SBH is infringing, inducing infringement of, and/or contributing to the infringement of the '297 Patent by making, using, offering to sell, selling, or importing, within this district or elsewhere in the United States, compositions or methods covered by the '297 Patent and/or by selling, offering for sale and/or importing compositions with instructions for use or promotions that cause and induce the user to infringe the claims in the '297 Patent, and/or by selling, offering to sell or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '297 Patent. SBH has actual knowledge of the '297 Patent. SBH became aware of the '297 Patent no later than June 30, 2020, when Plaintiffs sued SBH for infringement of the Patents-in-Suit in the Western District of New York. *See Bausch & Lomb Inc. et al. v. SBH Holdings LLC*, C.A. No. 6-20-cv-06451 (W.D.N.Y). Since filing the New York Lawsuit, SBH has continued infringing, inducing infringement of, and/or contributing to the infringement of the '297 Patent.

15. SBH is making, using, importing, offering to sell, or selling compositions containing a formulation of lutein, zeaxanthin, vitamins C and E, zinc, and copper, that are specifically described and claimed in the '297 Patent, including but not limited to SBH's MacularProtect® AREDS 2 and MacularProtect Complete® AREDS 2 products (the "MacularProtect® AREDS 2 products"). SBH is making, using, importing, offering to sell, or

selling such compositions for the use in treating or preventing age-related eye disease or for maintaining or preserving eye health or vision, which infringe the claims of the '297 Patent.

16. On information and belief, SBH is selling, offering for sale and/or importing compositions with instructions for use and promotions that cause and induce the user to infringe the claims in the '297 Patent, including but not limited to SBH's MacularProtect® AREDS 2 products. SBH is doing so with knowledge of the '297 Patent and with specific intent that its customers will infringe the '297 Patent.

17. On information and belief, SBH is selling, offering for sale and/or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '297 Patent.

18. On information and belief, SBH became aware of the '297 Patent on or after its issuance date of December 9, 2003. At the latest, SBH learned of the '297 Patent when Plaintiffs sued SBH for infringement of the Patents-in-Suit on June 30, 2020 in the Western District of New York. *See Bausch & Lomb Inc. et al. v. SBH Holdings LLC*, C.A. No. 6-20-cv-06451 (W.D.N.Y.). On information and belief, SBH has willfully infringed the '297 Patent by continuing to make, use, offer for sale, sell, or import SBH's MacularProtect® AREDS 2 products.

19. SBH is on notice that Bausch & Lomb's own products, including but not limited to PreserVision® AREDS and AREDS 2 Formula products, are proprietary.

20. The aforesaid sales and acts by SBH are without right, license or permission from Bausch & Lomb.

21. On information and belief, SBH intends to continue the sales and acts referred to in paragraphs 14-20.

22. Bausch & Lomb has been damaged by SBH's infringement of the '297 Patent and will be irreparably damaged if that infringement is not enjoined.

COUNT 2: PATENT INFRINGEMENT OF U.S. PATENT NO. 8,603,522

23. Bausch & Lomb incorporates herein and realleges as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 9 above.

24. Bausch & Lomb is a joint owner and licensee of all rights in the field of ophthalmology, including the right to enforce, of the '522 Patent which was duly and lawfully granted on December 10, 2013 to Stephen P. Bartels, Cara L. Baustian, George E. Bunce, Leon Ellenbogen, Frederick L. Ferris III, Jin Kinoshita, James C. Smith and David A. Souerwine for an invention in "Nutritional Supplement to Treat Macular Degeneration." PF Consumer Healthcare 1 is a joint owner of the '522 Patent. Pursuant to 35 U.S.C. § 207(a) and the exclusive license received from the U.S. government joint owner, including the right to enforce the '522 Patent, Bausch & Lomb can maintain this action without the U.S. government as a party. A true copy of the '522 Patent is attached as Exhibit C.

25. The '522 Patent describes and claims, among other things, methods for stabilization and/or treatment of visual acuity loss by reducing the risk of age-related macular degeneration and cataracts and for maintaining and preserving eye health and vision. The invention of the '522 Patent provides, *inter alia*, a method of administering a formulation of lutein-zeaxanthine combination or vitamin A in the form of beta-carotene (substituted or supplemented with lutein, zeaxanthine or a combination thereof), vitamin C, and vitamin E, as well as zinc and copper.

26. Bausch & Lomb markets and sells products for the methods covered by the '522 Patent within this district and elsewhere in the United States, including but not limited to its PreserVision® AREDS and AREDS 2 Formula products.

27. SBH is infringing, inducing infringement of, and/or contributing to the infringement of the '522 Patent by making, using, offering to sell, selling, or importing, within this district or elsewhere in the United States, products for the methods covered by the '522 Patent and/or by selling, offering for sale and/or importing compositions with instructions for use or promotions that cause and induce the user to infringe the claims in the '522 Patent, and/or by selling, offering to sell or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '522 Patent. SBH has actual knowledge of the '522 Patent. SBH became aware of the '522 Patent no later than June 30, 2020, when Plaintiffs sued SBH for infringement of the Patents-in-Suit in the Western District of New York. *See Bausch & Lomb Inc. et al. v. SBH Holdings LLC*, C.A. No. 6-20-cv-06451 (W.D.N.Y). Since filing the New York Lawsuit, SBH has continued infringing, inducing infringement of, and/or contributing to the infringement of the '522 Patent.

28. SBH is making, using, importing, offering to sell, or selling compositions containing a formulation of lutein, zeaxanthin, vitamins C and E, zinc, and copper, that are specifically described and claimed in the '522 Patent, including but not limited to SBH's MacularProtect® AREDS 2 products. SBH is making, using, importing, offering to sell, or selling such compositions for the use in treating or preventing age-related eye disease or for maintaining or preserving eye health or vision, which infringe the claims of the '522 Patent.

29. On information and belief, SBH is selling, offering for sale and/or importing compositions with instructions for use and promotions that cause and induce the user to infringe

the claims in the '522 Patent, including but not limited to SBH's MacularProtect® AREDS 2 products. SBH is doing so with knowledge of the '522 Patent and with specific intent that its customers infringe the '522 Patent.

30. On information and belief, SBH is selling, offering for sale and/or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '522 Patent.

31. On information and belief, SBH became aware of the '522 Patent on or after its issuance date of December 10, 2013. At the latest, SBH learned of the '522 Patent when Plaintiffs sued SBH for infringement of the Patents-in-Suit on June 30, 2020 in the Western District of New York. *See Bausch & Lomb Inc. et al. v. SBH Holdings LLC*, C.A. No. 6-20-cv-06451 (W.D.N.Y.). On information and belief, SBH has willfully infringed the '522 Patent by continuing to make, use, offer for sale, sell, or import SBH's MacularProtect® AREDS 2 products.

32. The aforesaid sales and acts by SBH are without right, license or permission from Bausch & Lomb.

33. On information and belief, SBH intends to continue the sales and acts referred to in paragraphs 27-32.

34. Bausch & Lomb has been damaged by SBH's infringement of the '522 Patent, and will be irreparably damaged if that infringement is not enjoined.

PRAYER FOR RELIEF

35. WHEREFORE, Plaintiff Bausch & Lomb respectfully requests the following relief:

A. A judgment and decree that United States Patent No. 6,660,297 remains valid and enforceable;

B. A judgment that SBH has infringed one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

C. A judgment that SBH has induced infringement of one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

D. A judgment that SBH has contributed to the infringement of one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

E. A judgment that SBH has willfully infringed one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

F. A judgment and decree that United States Patent No. 8,603,522 remains valid and enforceable;

G. A judgment that SBH has infringed one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

H. A judgment that SBH has induced infringement of one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

I. A judgment that SBH has contributed to the infringement of one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

J. A judgment that SBH has willfully infringed one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

K. A permanent injunction restraining and enjoining SBH, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions and methods claimed in Bausch & Lomb's United States Patent Nos. 6,660,297 and 8,603,522 or components or materials especially made or especially adapted

for use in an infringement of Bausch & Lomb's United States Patent Nos. 6,660,297 and 8,603,522;

L. An accounting of all damages to Bausch & Lomb arising from SBH's infringement, inducement of infringement, contributory infringement and willful infringement, and that such damages be awarded to Bausch & Lomb together with interest;

M. A permanent injunction ordering SBH to, *inter alia*, immediately cease all distribution and sale of the MacularProtect® AREDS 2 products;

N. An order that SBH recall all of the MacularProtect® AREDS 2 products currently in the marketplace;

O. An award of treble damages;

P. A grant of the costs of this action and reasonable attorneys' fees incurred by Bausch & Lomb in connection with this action; and

Q. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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